REMARKS

Applicants take this opportunity to thank Examiner Woodward and Examiner Palenik for the telephone interview conducted with Applicants' representative on January 16, 2009.

Upon entry of the amendments submitted herewith, claims 1 and 4-5 will be pending in this application. Claim 1 is under examination. Claim 4 has been withdrawn as being drawn to non-elected subject matter but has been amended to "depend from or otherwise require all the limitations of the allowable product claim" for consideration of rejoinder. Claims 2, 3 and 6-9 have been canceled without prejudice or disclaimer to the subject matter claimed within. Applicants, by canceling or amending any claims herein, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein or the original claim scope of any claim amended herein, in a continuing application.

Claim 1 has been amended to recite a "sterile ciclesonide-containing aqueous suspension comprising hydroxypropylmethylcellulose 2910, sterilized by autoclaving a ciclesonide-containing aqueous suspension, wherein the concentration of ciclesonide after autoclaving is 95% or more compared to that before autoclaving."

No new matter has been added within the meaning of 35 USC § 132.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 3 of the Official Action, claims 1 and 2 have been rejected under 35 USC § 102(b) as being anticipated by Karlsson et al. (US Patent Publication No. 2002/0065256).

The Examiner asserts that claims 1, 9 and 10 of Karlsson et al. describe each and

every element of pending claims 1 and 2. Applicants note that Karlsson et al. describe a sterile pharmaceutical formulation comprising a glucocorticosteroid and thickening agents.

In view of the remarks set forth herein, this rejection is respectfully traversed.

The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co.* of California, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); **MPEP § 2131**. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); **MPEP §2131**. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). Additionally as recently decided in *Net MoneyIn v. Verisign*, ___ F.3d ___ (Fed. Cir. 2008), "[b]ecause the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *See*, generally, *Net MoneyIn v. Verisign*, ___ F.3d ___ (Fed. Cir. 2008).

Currently amended claim 1 is directed to a sterile ciclesonide-containing aqueous suspension comprising hydroxypropylmethylcellulose 2910, sterilized by autoclaving a ciclesonide-containing aqueous suspension, wherein the concentration of ciclesonide after autoclaving is 95% or more compared to that before autoclaving. Claim 2 has been canceled without prejudice or disclaimer.

In contrast to the present claimed subject matter, Karlsson et al. is directed to a sterile pharmaceutical formulation comprising a glucocorticosteroid in an aqueous suspension and one or more pharmaceutically acceptable additives, diluents or carriers.

According to Karlsson et al. the additives include thickening agents. *See* Karlsson et al. at page 3, paragraphs [0032-0033]. However, unlike the presently claimed subject matter, Karlsson et al. do not teach or suggest a sterile ciclesonide-containing aqueous suspension comprising **hydroxypropylmethylcellulose 2910**, sterilized by autoclaving a ciclesonide-containing aqueous suspension, wherein the concentration of ciclesonide after autoclaving is 95% or more compared to that before autoclaving, as recited in currently amended claim 1. Applicants note that Karlsson et al. do describe that cellulose ethers may be used in order to form a stable suspension with a minimal tendency to agglomerate or form a sediment.

However, Karlsson et al. do not describe **hydroxypropylmethylcellulose 2910**, as recited in currently amended claim 1. Therefore, Applicants submit that Karlsson et al. do not satisfy the test set forth in *Net MoneyIn v. Verisign*. Namely, Applicants submit that Karlsson et al. do not disclose all elements of the claim "arranged as in the claim." *See*, generally, *Net MoneyIn v. Verisign*, ___ F.3d ___ (Fed. Cir. 2008). Accordingly, because Karlsson et al. do not recite each and every element of presently pending claim 1, Karlsson et al. cannot anticipate the presently claimed subject matter within the meaning of 35 USC § 102(b). In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

II. At pages 3 and 4 of the Official Action, claims 1-3 have been rejected under 35 USC § 103(a) as being unpatentable over Karlsson et. in view of the Material Safety Data Sheet (MSDS) for Metolose 60SH.

The Examiner has rejected claims 1-3 under USC § 103(a) as being unpatentable over Karlsson et al. in view of the MSDS for Metolose 60SH. The Examiner has obtained an MSDS from Shin-Etsu Chemical Company which, according to the Examiner, indicates

that Metolose 60SH is suitable for use as a thickening agent. The Examiner states that the hydroxypropylmethylcellulose 2910, recited in currently amended claim 1, is also known industrially as Metolose 60SH, and that hydroxypropylmethylcellulose 2910 and Metolose 60SH are chemically the same. The Examiner also asserts that, absent some demonstration of unexpected results from the presently claimed subject matter, it would have been obvious to one of ordinary skill of the art to employ the optimal grade of hydroxypropylmethylcellulose within the solution in order to achieve the best results.

In view of the following, this rejection is respectfully traversed.

A *prima facie* case of obviousness has not been established in the present application. To establish a *prima facie* case of obviousness, the Examiner must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04–1350, 550 U.S. at __, (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, *supra*, slip opinion at 13-

15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Applicants respectfully submit that a *prima facie* case of obviousness has not been established in the present application because there is no apparent reason to prompt a person of ordinary skill in the art to combine the elements disclosed in the cited references in the way the presently pending claims do, as required by *KSR*, *supra*. Further, any *prima facie* case of obviousness, if established, is rebutted by the data presented in Table 3 on page 14 of the present specification which illustrate that the improvement achieved by the presently claimed subject matter is more than the routine optimization of parameters that a person of ordinary skill in the art would have employed.

It is known in the art that drug content uniformity, *i.e.* uniform drug concentrations sampled from the upper, middle and lower portion of the suspension, of an aqueous suspension containing a water-insoluble drug tends to be decreased by autoclaving, even if the drug is chemically stable. *See,* for example, page 3 of the present specification. Applicants submit that the presently claimed ciclesonide-containing aqueous suspension comprising hydroxypropylmethylcellulose 2910 achieved unexpectedly superior ciclesonide concentration uniformities as compared to suspensions comprising other wetting agents. Applicants respectfully draw the Examiner's attention to the data in Table 3 on page 14 of the present specification. The data in Table 3 shows ciclesonide concentration uniformity after autoclaving for a ciclesonide aqueous suspension containing

hydroxypropylmethylcellulose 2910, as recited in currently amended claim 1 and exemplified by Example 2, compared to ciclesonide aqueous suspensions containing other wetting agents. The recovery rate of ciclesonide after autoclaving was calculated by taking the ciclesonide concentration before the autoclaving to be 100%. Aliquots of the bulk suspension were sampled from the upper, middle and lower portions of a glass container. As can be seen from the calculated ciclesonide recovery rates for Example 2 and Comparative Examples 3-7, the ciclesonide aqueous suspension containing hydroxypropylmethylcellulose 2910, as presently claimed, achieved unexpectedly superior ciclesonide concentration uniformity as compared to ciclesonide aqueous suspensions containing other wetting agents. In particular, the standard deviation of the ciclesonide recovery rates for the upper, middle and lower portions of the bulk suspension of Example 2 is approximately 0.05%, compared to standard deviations of as high as 7% for the upper, middle and lower portions of the bulk suspension of the Comparative Examples. Accordingly, Applicants respectfully submit that the ciclesonide aqueous suspension containing hydroxypropylmethylcellulose 2910, as presently claimed, achieved unexpectedly superior ciclesonide concentration uniformity as compared to ciclesonide aqueous suspensions containing other wetting agents.

In view of the remarks set forth herein, it is submitted that the unexpected results presented herein clearly rebuts any prima facie case of obviousness alleged by the Examiner. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw this rejection.

III. Request for Rejoinder of Withdrawn Claims

In the Official Action October 25, 2007, the Examiner stated at page 3, in relevant part:

> "Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder."

Applicants elected claims directed to the "product" in their Response dated November 21, 2007. Applicants believe that claim 1 is now in allowable form. Withdrawn claim 4 has been amended to depend from allowable claim 1. Withdrawn claim 5 depends from claim 4.

In view of the unexpected results data contained in the instant specification and the allowability of "product" claim 1, applicants now respectfully request that the Examiner now rejoin withdrawn claims 4-5 and allow them to proceed to grant along with claim 1.

CONCLUSION

In light of the foregoing, Applicant submits that the application is now in condition for allowance. If the Examiner believes the application is not in condition for allowance, Applicant respectfully requests that the Examiner contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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